Exhibit D

TENTH EDITION

TE LINDE'S OPERATIVE GYNECOLOGY

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Epithelialization

heir exposed location, the epithelial surfaces of stinal, urogenital, and respiratory tract as well elf are continually subjected to the physical and ma associated with the activities of daily living. ese surfaces are constantly replacing damaged or s through a process known as *epithelialization*. on occurs by migration and subsequent matura- ure epithelial cells from the deeper basal layers of ireas. If the cellular damage is confined entirely to n, the healing response is merely an exaggerated asic normal replacement process.

y involves the supporting connective tissue be- thelium, however, the other components of the sses, in addition to epithelialization, become in- injury severs blood vessels, the vessels retract, ess of hemostasis is initiated. If bleeding is not blood clot soon forms. This clot subsequently hydrates, and becomes a scab. Within 12 hours, om the surrounding epithelial surfaces begin mi- the injured surface. Epithelial cells move beneath iching it from the wound and sealing the surface. d sutured wounds, epithelialization generally pro- rtight seal within 24 hours of injury. This new ielial cells is initially thin and poorly attached to ig surface, rendering it susceptible to injury from rauma. Final epithelial healing is accomplished by n and maturation of the migrated cells and by scar rough fibroplasia.

Fibroplasia

by which wounds regain strength is termed *fibro-* plasia results in the production of the collagen form a fibrous scar and ultimately determines the of the healed wound. This process begins with iation of mesenchymal cells into fibroblasts. Fi- n migrate into the wound, apparently along fibrin iced during clot formation. Once at the injury site, roliferate and manufacture the glycoproteins and charides that make up the ground substance of ssue. Ground substance is an amorphous matrix ed to induce aggregation of collagen subunits and final orientation of the fibers.

ground substance is produced, fibroblasts begin to e basic building block of collagen-tropocollagen. n is a stiff elongated macromolecule of three heli- ned chains of amino acids consisting of two iden- is and one α2 chain. Within the ground substance oper pH, osmolality, and temperature, tropocol- les polymerize into collagen fibrils by forming co- with their neighbor. These fibrils bond with other n collagen bundles. It is not until 4 to 5 days after ie wound produces enough collagen to result in a ncrease in wound tensile strength. Before this time, held together only by fibrous adhesion. This time en wounding and an increase in tensile strength is referred to by Howes and Harvey as the "lag ound healing.

Wound Contraction

in which tissue heals is dependent on whether tis- is simply interrupted (as in a surgical incision) or ved (as in an avulsion injury). In both types of in- collagen for structural support. However, when large amounts of tissue are missing, the edges of the wound must be brought closer together so that the previously noted tissue responses can repair the defect. This process is known as *contraction*. Contraction of wound margins begins about 5 days after injury and corresponds with the fibroplasia phase of healing. Because this process can be inhibited by cytochrome poisons, such as potassium cyanide, and by smooth muscle relaxants, older theories attributing wound contraction to passive collagen changes have been discarded. Instead, wound contraction appears to be an active process produced by contractile proteins within the fibroblasts. If the area is too large for contraction to bring the edges together, the wound remains covered with granulation tissue, or if small enough, it is covered with epithelium only. Epithelialization of such a wound prevents weeping, but without the normal underlying supporting stroma, it remains too fragile to provide lasting protection. Pathologic progression of skin contraction ultimately may result in restriction of joint or limb mobility. This deformity is termed *contracture* and should not be confused with contraction.

Scar Maturation

The bulky scar formed during the fibroplasia phase consists of randomly oriented soluble collagen fibers. This scar has little tensile strength. During scar maturation, the disordered fibers are replaced with fibers arranged in a more orderly fashion, producing a denser and stronger scar. Collagen fibers also continue to form covalent bonds within fibrils as well as between adjacent fibrils and fibers, resulting in a continued increase in wound tensile strength over time. This maturation process may continue for years.

During scar maturation and remolding, the breakdown of old disordered collagen slightly exceeds production of new organized collagen fibers. The resulting new scar is softer and less bulky than the original scar but also is stronger because of its more organized and extensively cross-linked nature. However, if collagen production exceeds breakdown, then a keloid or hypertrophied scar results.

Surgical Wound Healing

Depending on the manner of wound closure, three types of surgical wound healing are recognized: primary, secondary, and third intention. Figure 13.1 illustrates these types of wound healing.

Primary Intention

Healing occurs by primary intention if the wound layers are reapproximated following injury. This apposition of tissue layers allows healing to occur in a minimum of time, with no separation of wound edges and with minimum scar formation. This is the desired mode of healing for surgical incisions.

Secondary Intention

It has been known for centuries that a wound has a higher resistance to infection when left open rather than closed. This was demonstrated experimentally in dogs by Bilroth, who applied dressings soaked in liquid feces and pus to wounds. Wounds left open remained healthy in appearance, whereas those that were subsequently closed became infected. As a result, contaminated or infected surgical wounds often are left unapproximated and allowed to close spontaneously. This type of wound healing

CHAPTER 37 ■ STRESS URINARY INCONTINENCE

ALFRED E. BENT

DEFINITIONS

Cystometrics—Tests of bladder function, including bladder sensation, capacity, and compliance. These tests may be simple clinical evaluations of bladder filling and emptying or may involve electronic measurement of bladder, urethral, and intraabdominal pressures.

Hypermobile stress incontinence—Stress incontinence caused by loss of anatomic support of the urethra and bladder base.

Intrinsic sphincter deficiency—Urinary incontinence that is due to dysfunction of the urethral sphincter mechanism.

Stress urinary incontinence—Involuntary leakage of urine from the urethra caused by increased intraabdominal pressure (coughing, straining, etc.).

Urodynamic stress incontinence—Involuntary leakage of urine during increased abdominal pressure in the absence of a detrusor contraction.

Urinary incontinence is a condition that affects 30% to 40% of older American women, with the majority afflicted with stress urinary incontinence (SUI). Conservative therapy helps a large number of these patients but cures relatively few. Surgical approaches for SUI have become more and more common, and have moved to delivery through minimally invasive surgical techniques. The purpose of this chapter is to detail the required evaluation before surgical intervention, then describe the surgical procedures used most effectively, along with the indications, results, and complications.

Stress urinary incontinence is defined by the International Continence Society as a condition defined by urodynamic observations associated with characteristic signs or symptoms. *Urodynamic stress incontinence* is defined as the involuntary leakage of urine during increased abdominal pressure in the absence of a detrusor contraction. Under the category of lower urinary tract symptoms, SUI is a storage disorder for which the characteristic symptom is the involuntary leakage of urine on effort or exertion, or on sneezing or coughing. The sign of SUI is the observation of involuntary leakage from the urethra synchronous with exertion or effort, such as sneezing or coughing. Current terminology refers to the condition described by both symptoms and urodynamic findings.

Stress incontinence has been divided into **hypermobile stress incontinence**, caused by anatomic defects, and **intrinsic sphincter deficiency**, with incontinence resulting from a poorly functioning urethra. This separation has become less distinct with time. SUI may include a wide spectrum of varying degrees of disruption of normal anatomy causing hypermobility or, somewhat paradoxically, scarring and fixation of these same tissues. Urethral sphincter function may be minimally altered so as not to be discernable on testing, or it may be severe. Most experts in the field are of the opinion that there is a contribution of each kind of dysfunction in most patients. The development of SUI has been attributed to a number of causes, with childbearing thought to be a dominant role in altering structural function (Table 37.1).

INITIAL EVALUATION

In 1996, the Agency for Health Care Policy and Research published its consensus guidelines for the evaluation and management of urinary incontinence. These recommendations from a panel of experts include the following: a thorough history (including voiding diary), physical examination, postvoid residual, and urinalysis.

More recently, the 3rd International Consultation on Incontinence held in Monaco (June 26–29, 2004) has published a series of management algorithms, including one for women with incontinence. The basic evaluation includes history; urinary symptom assessment, including a frequency-volume chart and questionnaire; assessment of quality of life and desire for treatment; cough stress test; urinalysis; assessment of voluntary pelvic floor contraction; and assessment of postvoid residual urine.

INITIAL MANAGEMENT

The recommendations for initial management do not require detailed testing, but treatment is based on a presumptive diagnosis of SUI. The first-line therapies commence with lifestyle interventions, which include weight reduction, smoking cessation, and dietary and fluid modification. Estrogen deficiency requires treatment followed by reassessment. Supervised pelvic floor muscle training and bladder training are recommended. The key word here is *supervised*. Patients will not and can not manage the proper therapy on their own. An appropriate duration of therapy is 8 to 12 weeks before reassessment for further treatment. Vaginal support devices can be included in the treatment options, depending on availability of the product, ability of the patient to manage the product, patient acceptance, and cost. In Europe, there is drug therapy available in the form of a dual serotonin and noradrenalin reuptake inhibitor, which has well-documented efficacy in large placebo-controlled drug studies.

EVALUATION BEFORE SURGERY

The American College of Obstetricians and Gynecologists Practice Bulletin issued in 2005 describes the evaluation of patients with symptoms of SUI. In addition to a focused history and

TABLE 37.1

FACTORS CONTRIBUTING TO STRESS URINARY INCONTINENCE

Factor	Possible mechanisms
Childbirth	Disruption of normal anatomy Pelvic nerve injury
Aging	Estrogen deficiency Tissue degradation Peripheral neuropathy
Iatrogenic: postsurgery	Disruption of normal anatomy Pelvic nerve injury Loss of tissue elasticity Loss of vascular cushion
Chronic obstructive pulmonary disease, chronic heavy lifting Chronic constipation	Straining causing stresses on normal anatomy and pelvic nerve injury
Iatrogenic: medication side effect	Loss of urethral tone
Pelvic radiation	Peripheral neuropathy Loss of tissue elasticity Loss of vascular cushion
Obesity	Increased intraabdominal pressure causing stresses on normal anatomy and pelvic nerve injury
Neurogenic disease	Loss of normal reflexes, pelvic floor tone, and urethral tone
Congenitally poor tissues: • Connective tissue disorder • Genetic predisposition	Poor anatomic integrity

physical examination, a urine culture, urine analysis, and renal function blood tests are indicated. Office evaluation of bladder filling and voiding should be done, and specialized tests of bladder function, including cystometry and cystourethroscopy, may be helpful in some patients. Guidelines for operating on patients with urethral hypermobility–type stress incontinence are shown in Table 37.2. This criteria set does not include urodynamic evaluation. The guidelines from the International Consultation on Incontinence recommended urodynamics to diagnose the type of incontinence. Urethral function testing by urethral pressure profile or leak-point pressure was optional. Basically, the recommendation is that in addition to the basic evaluation already completed, a cystometrogram is recommended to diagnose detrusor overactivity or stress incontinence.

The patient having a primary repair for SUI should have detailed history, physical examination with assessment for prolapse, frequency-volume chart (voiding diary), symptom questionnaire, urinalysis, assessment of bladder-neck mobility (Q-tip test or imaging), and residual urine determination. Bladder-neck mobility can be assessed by inserting a lubricated Q-tip into the urethra to the bladder neck and assessing for movement greater than 30 degrees from horizontal with straining. In the patient who has symptoms that are mixed (stress and urge) or whose voiding diary does not fit a pattern of pure stress incontinence, further evaluation is indicated.

TABLE 37.2

ACOG GUIDELINES FOR PRIMARY SURGERY FOR STRESS URINARY INCONTINENCE

Confirmation of indication	Actions before the procedure
Documentation of stress incontinence	Document normal voiding habits
Identify and manage transient causes of stress incontinence	Document normal neurological examination
Demonstrate stress loss and confirm low residual urine	Document absence of prior incontinence or radical surgery Document absence of pregnancy Counsel patient regarding alternative therapy

ACOG, American College of Obstetricians and Gynecologists.

The patient who has failed prior surgery or who has symptoms other than straightforward stress incontinence merits urodynamic evaluation and cystoscopy before surgery. Other options include imaging or videourodynamics.

SURGICAL TECHNIQUES FOR THE TREATMENT OF STRESS INCONTINENCE

More than 200 procedures have been described in the literature for the treatment of stress incontinence (Table 37.3). This reflects a combination of the alteration of techniques and approaches of established and effective procedures and the introduction of newer technologies and materials. In today's surgical practice, it is well established that performing an anterior repair or Kelly plication for the treatment of SUI is substandard compared with more effective procedures. This procedure was described in the 19th century; although it remains a recognized therapy for central defect cystocele, the most current international recommendation for use in patients with stress incontinence is in women who prefer to sacrifice some chance of becoming continent for a reduced chance of complication. Because of significant recurrence rates at even 1 and 2 years of follow-up, long-needle procedures—such as the Peyera, Stamey, or Raz procedures—are not recommended. Currently, the two primary forms of surgery for SUI are retropubic urethropexy and sling procedures. Injection of urethral bulking agents also is used as a less invasive intervention for SUI in certain patients. A comprehensive listing is provided in Table 37.3, but the procedures presented in detail will be those in current widespread use.

Retropubic Urethropexy

The gold-standard surgical treatment of SUI in patients with a mobile bladder neck and normally functioning urethra has been accomplished through a retropubic approach using either

TIME LINE OF SIGNIFICANT SURGICAL PROCEDURES FOR STRESS INCONTINENCE

Anterior repair
- Schultz 1870—anterior repair
- Kelly plication 1913—wedge of tissue to support ureterovesical junction
- Ingelman Sundberg 1951–1952—bulbocavernosus

Sling
- von Giordano, 1907—gracilis muscle
- Goebell 1910—pyramidalis muscle
- Frangenheim 1914—abdominal wall fascia with pyramidalis
- Stoeckel 1917—same as Frangenheim
- Price 1933—fascia lata
- Aldridge 1942—rectus fascia
- Ridley 1974—description of sling in textbook
- Zoedler 1961—gauze hammock synthetic sling

Paravaginal repair
- White 1909—original description
- Richardson 1981—renewal of White technique

Retropubic
- Marshall-Marchetti-Krantz 1949
- Burch 1968
- Tanagho 1976—Burch modification
- Vancaillie 1991—laparoscopic Burch

Needle suspension
- Pereyra 1959
- Stamey 1973
- Raz 1981
- Gittes 1987

Periurethral bulking
- McGuire 1994—Contigen® injection

Tension-free synthetic tape
- Ulmsten and colleagues 1996—TVT (tension-free tape)
- DeLorme 2001—Transobturator tension-free tape

a Burch retropubic urethropexy or Marshall-Marchetti-Krantz (MMK) procedure. Although retropubic urethropexy has been widely used and is very effective, the newer midurethral, tension-free sling procedures are very popular, effective, and easier to perform.

The traditional approach to the retropubic space has been through a low transverse incision, which has gradually diminished in size to a minilaparotomy-type approach (Fig. 37.1). A Foley catheter keeps the bladder empty and helps identify the bladder neck. Entry into the peritoneal cavity is avoided unless there is a surgical indication. After opening the rectus fascia, the rectus muscles are separated, and then gentle downward pressure just behind and lateral to the symphysis allows approach to the pelvic sidewall and endopelvic fascia. If there has been prior surgery in this area, sharp dissection is required to separate the rectus muscle from the underlying preperitoneal tissue and bladder. Depending on the incision size, a self-retaining retractor may be used. The bladder is retracted superiorly with the aid of a moist pack, and the inferior part of the incision is retracted to expose the bladder. Following exposure of the retropubic space, the bladder neck is identified by palpation of a Foley catheter bulb, and it may be marked with hemoclips if desired. The anatomic landmarks and points of attachment of endopelvic fascia can then be identified (Fig. 37.2).

When performing a Burch retropubic urethropexy, the paraurethral tissue is exposed either with a "daisy sponge" (three 4 × 4 sponges on a sponge stick) or by using a moist sponge and narrow retractor. The best instrument for this is a Miyazaki all-purpose lighted retractor. The paraurethral areas may be cleared of fat that overlies the pubocervical fascia (fibromuscular layer of the vagina). The pubocervical tissue is elevated with a vaginal finger, and the overlying tissue and bladder are mobilized medially and superiorly away from the site of suture placement using a small dissecting sponge or "peanut" (Fig. 37.3). The large veins in this area are avoided, if possible, but may require control with suture, hemoclips, or cautery. The most important aspects of the development of the retropubic space dissection are exposure and retraction, and identification of the white endopelvic fascia (also called pubocervical fascia or fibromuscular layer of the vagina). Permanent sutures are placed on either side and 2 cm lateral to the urethra into the endopelvic fascia (avoiding full thickness), one set at the bladder neck and the second set at midurethra (Figs. 37.4 and 37.5). One or both arms of each suture are sutured through the ipsilateral Cooper's ligament and then tied from inferior to superior with an assistant elevating the vagina (Fig. 37.6).

An MMK procedure is performed by identifying the urethra with the aid of the Foley catheter (Fig. 37.7). Sutures are placed on either side of the urethra in a paraurethral location quite close to the urethra (Fig. 37.8). Bilateral permanent sutures are placed at the bladder neck and usually at least one set is placed just distal to this. These sutures are attached to the fibrocartilage of the symphysis pubis. Some surgeons open the bladder dome to locate the bladder neck by direct vision for exact suture placement at the bladder neck.

The aim of both procedures is to reestablish the intraabdominal location of the proximal urethra and urethrovesical junction, and to minimize descent of the bladder neck or urethrovesical junction, thus allowing normal pressure transmission to this crucial area during times of increased intraabdominal pressure. Cure rates for these procedures range from 85% to 90% at 1 to 5 years and greater than 70% at 10 years.

These procedures can be performed in concert with an abdominal hysterectomy or alone through a retropubic approach without opening the peritoneal cavity. Minilaparotomy techniques allow incisions as small as 5 cm to accomplish the suspension.

Laparoscopic Burch urethropexy became very popular in the mid-1990s. The approach could be either intraabdominal or extraperitoneal, and numerous modifications to the original Burch procedure were described, including using only two sutures; substituting mesh; or using tacks, anchors, and other tools to elevate the bladder neck. These variations significantly lowered cure rates as compared with traditional open urethropexy. Placement of four permanent sutures identical to an open procedure, though, has yielded similar 1- and 2-year cure rates as an open Burch (93% and 89%, respectively). In a prospective randomized trial of 62 laparoscopic and 28 open Burch procedures followed by urodynamics at 1 year, the cure rates were 93% for the laparoscopic and 88% for the open group. However, the more recent introduction of tension-free tape procedures made the use of laparoscopic Burch markedly less frequent, and it is now generally performed only with other intraabdominal reconstructive surgery.

Another procedure in the category of a retropubic approach is the paravaginal defect repair, first described by White and revitalized with Richardson and Shull. However, this procedure is for correction of lateral defect cystocele and not for treatment of SUI.

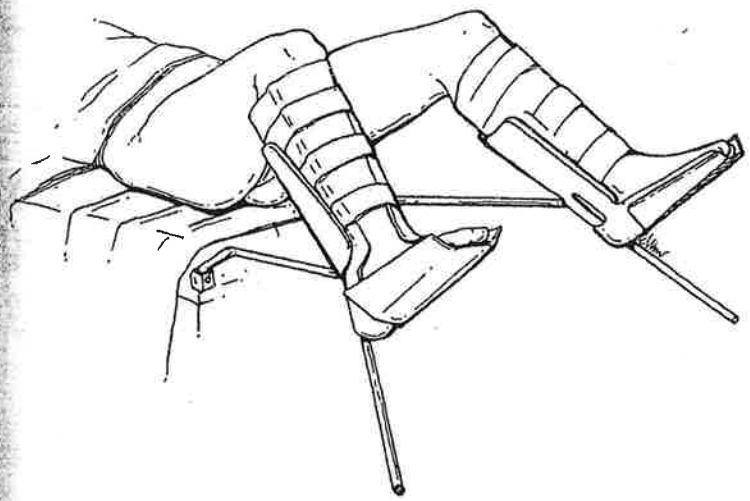


FIGURE 37.1. Positioning the patient for retropubic urethropexy in Allen universal stirrups to allow vaginal and abdominal access.

Tension-free Midurethral Slings

Tension-free slings are surgical procedures using a polypropylene mesh to support the midurethra without tension, a technique first described by Ulmsten and colleagues. Long-term follow-up has been reported with cure rates of approximately 85%. The original technique uses a retropubic approach, but the transobturator approach is fast becoming the most common tension-free sling technique performed worldwide for primary SUI. The appeal of a tension-free midurethral sling is that it is an effective, minimally invasive technique using local anesthetic and intravenous sedation in a day-surgery setting.

Many products are now marketed for this type of sling (Table 37.4). Some surgeons fashion their own sling from polypropylene soft mesh and place it without the aid of specially devised needles and kits. The manufactured products have a protective plastic sheath, allowing easy movement and adjustment of the sling under the urethra (Fig. 37.9).

The anesthetic for the procedure is injected as a solution of lidocaine hydrochloride diluted to 0.25% (1/4%) strength. Because the approximate maximum safe dose is 30 mL of a 1% solution, the 0.25% (1/4%) solution will provide 120 mL. Epinephrine may be used in the mixture, and with an original concentration of 1/100,000, the dilution ends up as 1/400,000. Alternatively, bupivacaine HCl may be used for local infiltration. The maximum dose of bupivacaine is 225 mg

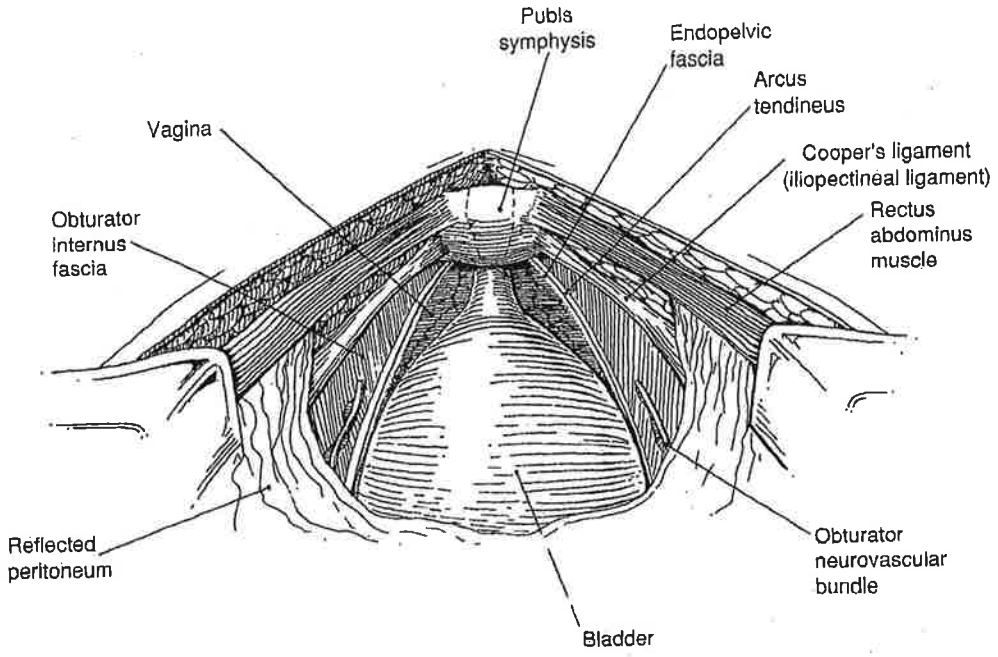


FIGURE 37.2. Anatomic landmarks in the space of Retzius.

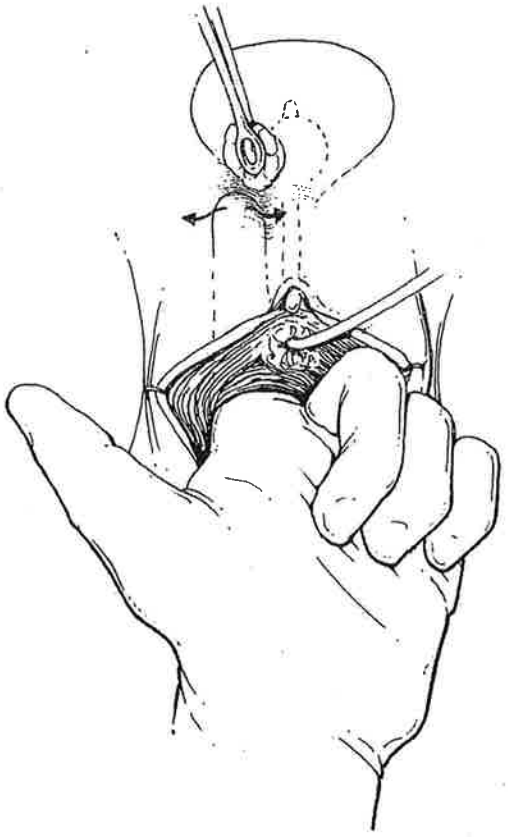


FIGURE 37.3. Dissection of bladder medially to expose endopelvic fascia. The finger of the vaginal hand elevates the vagina while the instrument pushes medially against the finger.

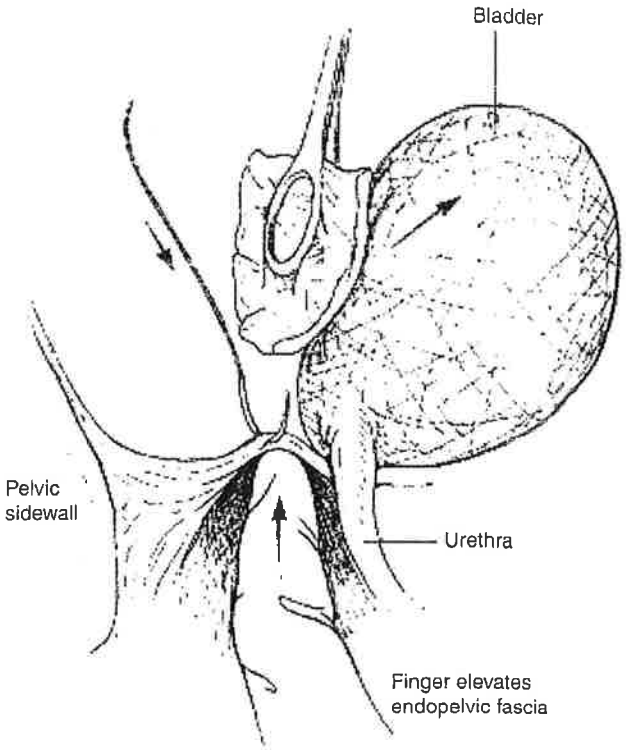


FIGURE 37.5. Medial displacement of the bladder for Burch suture placement. (From Robinson D, Norton PA. Diagnosis and management of urinary incontinence. In: William WM, Stovall TB, eds. *Gynecologic surgery.* New York: Churchill Livingstone; 1996:713.)

with epinephrine and 175 mg without epinephrine. In the traditional tension-free tape, 30 mL of solution is injected suprapubically on each side to include skin and subcutaneous tissues, rectus fascia, tissue immediately adjacent to the symphysis pubis, and endopelvic fascia. Then 20 mL of the solution is placed bilaterally by a vaginal approach, extending laterally from the midline into the endopelvic fascia and under the descending pubic rami. Five to 10 mL is placed under the midurethra. The bladder is emptied. A 1- to 2-cm incision is made under the midurethra. For traditional tension-free tapes, a 2 cm tunnel is made with Metzenbaum scissors at a 45-degree angle toward the descending pubic ramus on each side. A rigid

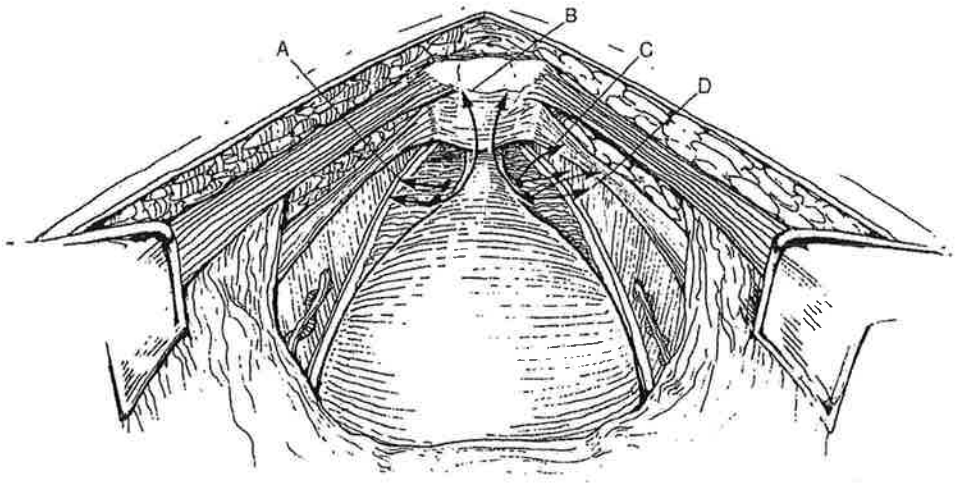


FIGURE 37.4. Points of attachment of endopelvic fascia at retropubic bladder neck suspension. A: Arcus tendineous fascia pelvis. B: Periosteum of pubic symphysis. C: Cooper's ligament. D: Obturator internus fascia.

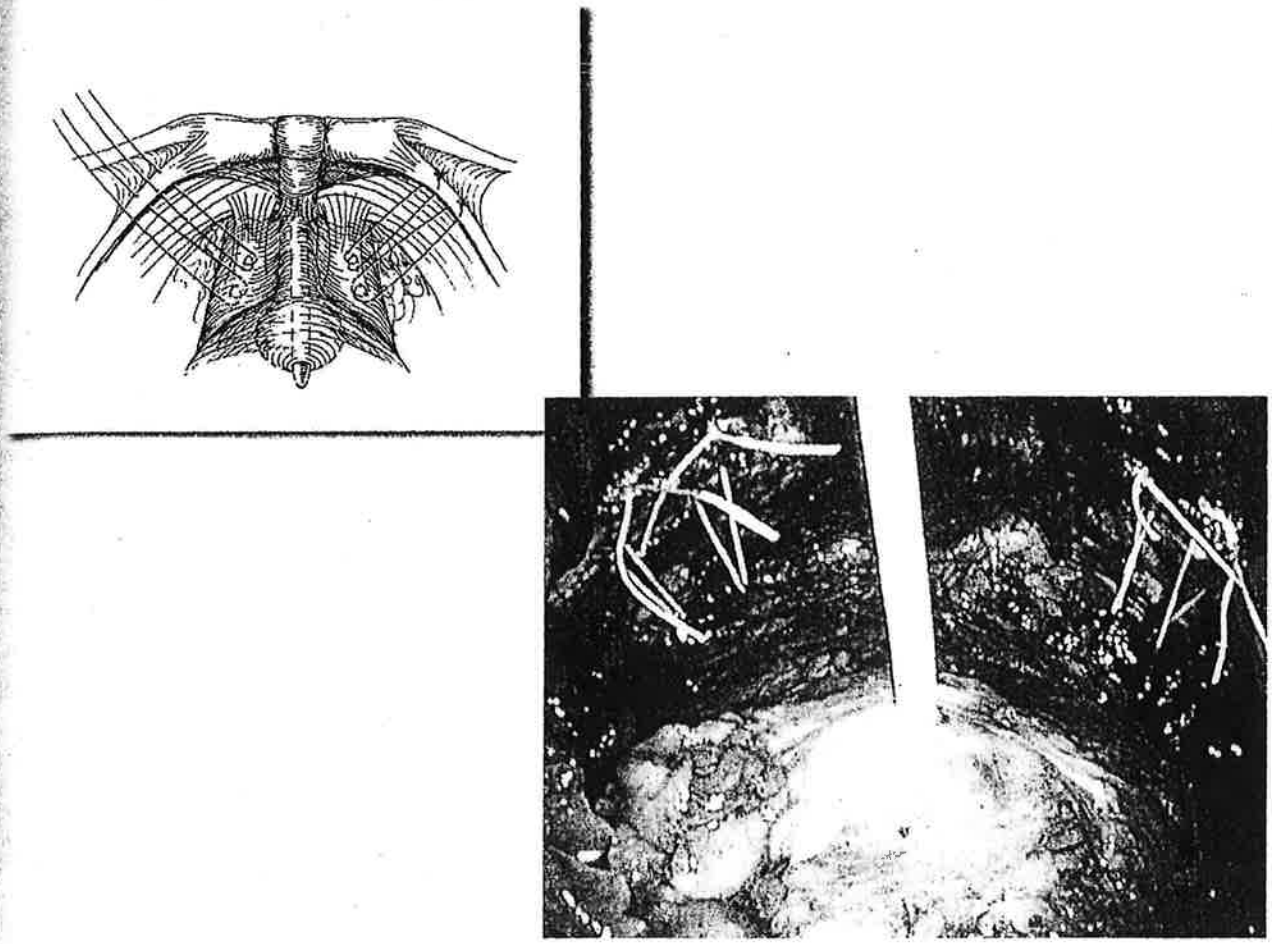


FIGURE 37.6. Placement of Burch colposuspension sutures. Sutures are placed in the endopelvic fascia, then passed through Cooper's ligament and tied.

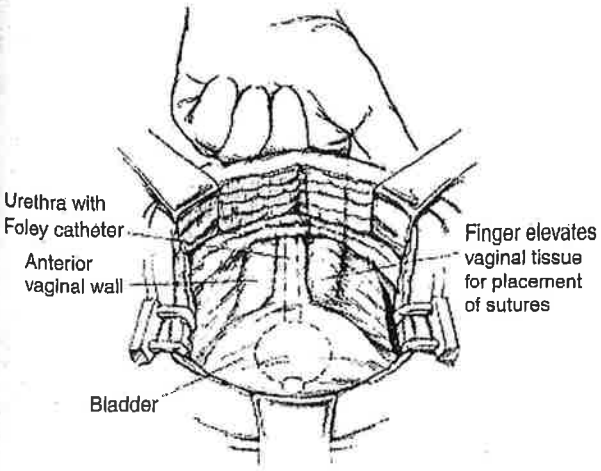


FIGURE 37.7. Marshall-Marchetti-Krantz procedure. (From Robinson D, Norton PA. Diagnosis and management of urinary incontinence. In: William WM, Stovall TB, eds. *Gynecologic surgery.* New York: Churchill Livingstone; 1996:716.)

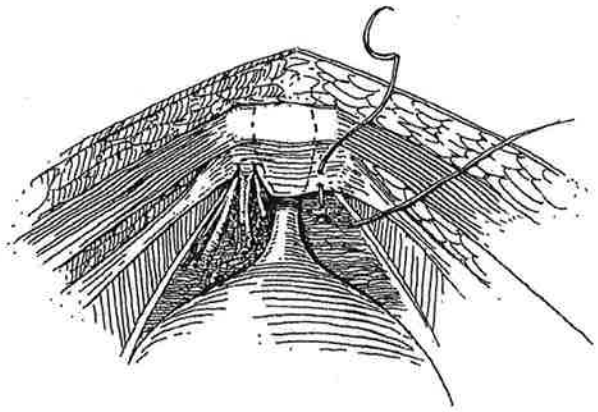


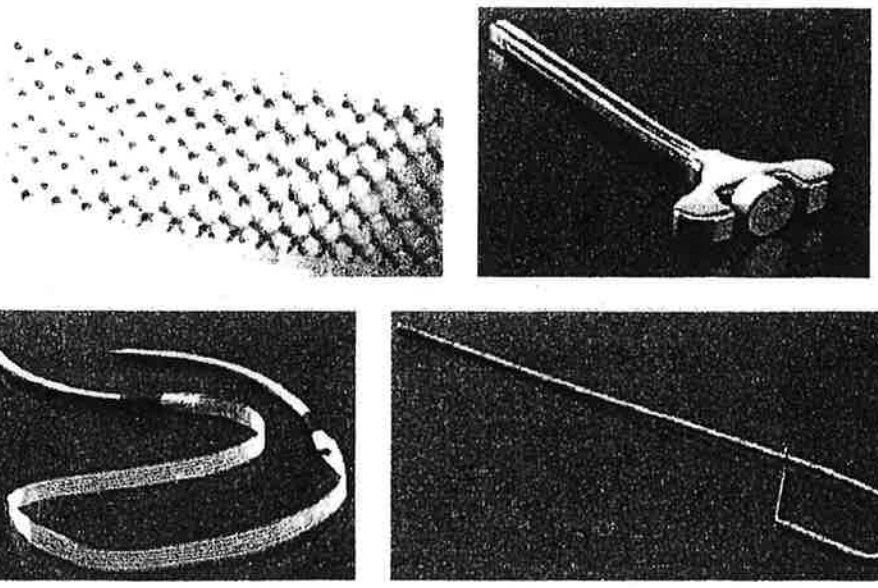
FIGURE 37.8. Suture placement for Marshall-Marchetti-Krantz operation. Sutures are placed into the endopelvic fascia along the urethra and fixed into the periosteum or fibrocartilage along the back of the symphysis pubis.

TENSION-FREE POLYPROPYLENE MESH PRODUCTS

Trade name	Company	Location
TVT	Gynecare (Ethicon, Inc.)	Somerville, NJ
Obturator system	Gynecare (Ethicon, Inc.)	Somerville, NJ
Sparc	AMS	Minneapolis, MN
Uretex	C R Bard Inc.	Covington, GA
IVS Tunneller	Tyco (U.S. Surgical)	Norwalk, CT
Remeex	Neomedic	Barcelona, Spain
ObTape™	Mentor	Santa Barbara, CA
Monarch	AMS	Minnetonka, MN

catheter guide is placed in a 18 French catheter; this is placed into the urethra and directed laterally to the side on which the surgeon is working so as to deviate the bladder to the opposite side. The delivery needle with detachable handle is placed into the tunnel by an initial lateral direction, then directed toward the ipsilateral shoulder while the opposite-hand index finger guides the needle under the descending pubic ramus. The needle hugs the pubic ramus as the endopelvic fascia is penetrated, and then is advanced until the tip appears suprapubically (Fig. 37.10). The needle tip is passed just through a 5-mm skin incision, and the detachable handle is removed and placed on the needle passer for the other side. The tape is passed on the opposite side, and the handle removed. Cystoscopy is performed after each pass, or, alternatively, after both passes have been made. If there is no bladder perforation, the needles are advanced and pulled completely through the suprapubic area while viewing the bladder with the cystoscope. The needles are removed from the sling device. The sling with protective sheath is tightened over a number 8 Hegar dilator or other instrument. A clamp is positioned to grasp only the plastic sheath, and, while tension is maintained on the Hegar dilator to prevent the sling from becoming too tight, the plastic sheaths are gently pulled free from the mesh. The excess sling arms are cut flush to the skin surface. The vaginal and skin incisions are closed. The sling is not sutured to any underlying tissue, and the composition of the mesh allows tissue ingrowth to fix the sling in place. A pack is not usually placed unless there has been considerable bleeding. A Foley catheter is placed; or, alternatively, the patient may go to recovery without a catheter. A voiding trial is initiated in the recovery room; if the patient does not pass, she performs self-catheterization, or a Foley catheter is placed overnight. The catheter is removed by the patient the following morning, and she comes to clinic for assessment of voiding function.

The abdominal approach commences with the same vaginal dissection. A catheter guide is usually not used. The abdominal needle passer is passed through a small incision on either side of the midline just above the symphysis pubis and is guided along the back of the symphysis until it passes under the descending pubic ramus and comes into contact with the vaginal finger. It is guided into the vaginal incision similar to needle suspension procedures, such as Stamey, Raz, and Pereyra. Cystoscopy is performed to ensure the needle passers have not penetrated the bladder. The mesh is attached to the needle passers and pulled from the vaginal incision through the retropubic space to the abdominal site. The remainder of the procedure is the same as the vaginal route. Complications are similar to tension-free



Vaginal approach for tension-free vaginal tape procedure. Gynecare TVT tension-free support for incontinence. Materials include a catheter guide to retract the bladder away from the working area, the tape material attached to two insertions needles, and the handle to attach to the needles for insertion. (Gynecare, a Division of Ethicon, Inc).

FIGURE 37.10. Insertion of vaginal tension-free tape. A: Vaginal guidance of needle under descending pubic ramus along back of symphysis. B: Pressure over skin of abdomen to allow needle to penetrate abdominal skin. C: Both needles passed through retropubic space and resting on abdomen. (With permission: Klutke J, Klutke C. The promise of tension-free vaginal tape for SUI. *Contemporary Urology® Archive*. 2000; October: Figures 4, 6, and 7.)

vaginal tape (TVT) except for fewer described severe problems with vascular or bowel injury. Bladder perforation occurs with equal frequency.

The most serious complications after the first 500,000 cases of TVT procedures are shown in Table 37.5. There were seven deaths from that group, which included five after undiagnosed bowel perforation, one from uncontrolled bleeding in the retropubic space in a woman with a bleeding disorder, and one after a bowel perforation in which no additional information could be obtained. Major vascular injury may be prevented by using universal Allen stirrups. The insertion needle must not stray laterally. Smaller venous channels are frequently penetrated and are managed by pressure for 5 minutes or placement of a vaginal pack. Moderate bleeding may be controlled by a Foley catheter with 50 mL in the balloon to tamponade the bleeder against a pack in the vagina. Occasionally, a retropubic space hematoma will develop; but it is self-limited, and the usual treatment is observation. Bladder perforation occurs 2% to 4% of the time and is usually managed by withdrawal and reinsertion of the needle. When this occurs, a Foley catheter is recommended for 1 to 2 days, and antibiotic coverage provided. Bladder perforation may be prevented by infiltration of the dilute local anesthetic in large volume amounts, keeping the bladder empty, and directing the bladder away from the operative site with the rigid catheter guide. Bowel perforation may be prevented by imaging prospective patients who have had prior retropubic surgery and who may have bowel adherent in the cul-de-sac in close proximity to the retropubic area.

Frequent delayed complications include voiding dysfunction, urgency, and urinary tract infection (Table 37.6). About half of patients will void by the time of discharge from day surgery, and most are voiding well by the following day. There is a 2% to 5% persistent urinary retention rate, and these patients require sling revision. This is best performed in the first 4 to 6 weeks after surgery before advanced scarring around the mesh. The tape has usually migrated somewhat proximally along the urethra and needs to be exposed by sharp dissection, then loosened or cut to allow retraction of the mesh away from the underside of the urethra. Continence is maintained in most patients, and the release of the sling allows normal voiding in most cases. Urinary tract infection may be prevented by preoperative antibiotics, but there is still a 7% to 8% incidence of urinary tract infection in the first 2 months postoperatively. Urgency with some urge incontinence occurs in 10% to 12%; although time resolves a lot of this, a number of patients require medical intervention. Release or loosening of the sling may help resolve severe urgency symptoms. Mesh erosion is a delayed complication, occurring in 1% of patients, and usually is managed by excision of the exposed mesh and resuture of the vagina.

The transobturator approach (TOT) theoretically has safety factors that may make it preferable to the original TVT

TABLE 37.5

REPORTED MAJOR TENSION-FREE VAGINAL TAPE COMPLICATIONS[a] BASED ON 500,000 CASES

Complication	United States	Outside United States	Total	Percent
Vascular injury	7	37	44	0.009
Vaginal mesh exposure	43	17	60	0.012
Urethral erosion	20	0	20	0.004
Bowel perforation[b]	16	12	28	0.006
Nerve injury	3	1	4	0.0008
Urinary retention	48	45	93	0.019
Hematoma formation	4	16	20	0.004

[a]Gynecare report to Food and Drug Administration as of September 26, 2003.
[b]Seven deaths have been reported, six associated with bowel perforation.

MINOR COMPLICATIONS IN 1,455 TENSION-FREE VAGINAL TAPE CASES[a]

Incidence	N/1,000	Percent
Minor voiding difficulty	76	7.6
Urinary tract infection	41	4.1
Bladder perforation	38	3.8
Postoperative urinary retention	23	2.3
Retropubic hematoma	19	1.9
Wound infection	8	0.8

From Kuuva N, Nilsson CG. *Acta Obstet Gynecol Scand* 2002;81:72.
[a]A nationwide analysis of complications associated with the tension-free vaginal tape.

approach. It is placed more horizontally and should interfere with voiding even less than a TVT. Local infiltration of dilute lidocaine or Marcaine is carried out along the tracks of needle passes. There are two basic types of transobturator surgeries for stress incontinence. One is an outside-in technique, which emphasizes speed, safety, and ease of placement. The vaginal incision needs to be large enough to insert a finger to reach to the ischiopubic ramus, and the thumb of the same hand grasps the outline of the ramus in the genitofemoral fold between labium majus and the thigh. A point in the groin fold level with the clitoris is selected and a 5-mm incision made on each side. The needle passer is inserted perpendicularly and guided by the finger until it penetrates the obturator membrane (Fig. 37.11). The needle is then rotated under the pubic ramus, and the vaginal index finger guides it into the vaginal incision. The tightening of the sling is the same as the TVT.

The inside-out TOT starts with local infiltration of dilute anesthetic. The incision may be slightly smaller than the outside-in TOT. Scissor dissection proceeds on one side until the obturator membrane is penetrated with the scissor tips. A metal winged guide is placed into the defect in the obturator membrane. The needle passer is placed along the direction of the winged guide and then rotated while the handle is moved inferiorly to a vertical position. The needle passer exits 1 cm lateral to the groin fold about 2 cm superior to the urethral meatus and parallel to the clitoris. The tape is retrieved, and tightening follows the same pattern as with the technique described above. The same-day patient attempts to void in recovery; if unsuccessful, she uses self-catheterization or has a Foley placed overnight.

The transobturator tape does not have a retropubic passage and therefore avoids the major complications of retroperitoneal vascular injury, bowel injury, and bladder perforation. Because of the horizontal placement for TOT, the incidence of postoperative voiding dysfunction is considered to be less, though no large randomized trial has definitively shown this (Fig. 37.12). There remains the possibility of damage to the obturator vessels and nerve during passage of the needle, but this can be avoided by following the procedure as described. There have been isolated reports of bladder perforation, and it may still be appropriate to carry out cystoscopy with urethral inspection at the end of the procedure, especially in women with significant prolapse. There are still the same complications of bleeding, hematoma, dysuria, urgency, and bladder infections as with TVT. Abscess formation in the ischiorectal fossa has been reported, but it is very uncommon. Occasionally, there is persisting groin pain or irritation with movement.

FIGURE 37.11. Transobturator tension-free tape (TOT) approach. The finger is placed in the vaginal dissection into the space of Retzius while the thumb hooks the tissue at the genital-crural fold. The specialized needle is passed from either outside to inside, or vice versa, and the tape is attached and pulled through the space. (With permission: Pelosi MA II, Pelosi MA III. New transobturator sling reduces risk of injury. *ObGyn Management* 2003;15:17.)

The tension-free sling is thought to work by forming a solid buttress under the midurethra, allowing the mobile bladder neck to descend and rotate with increased intraabdominal pressure, and compress the urethra against the sling. Most efficacy reports are in the 85% range for both TVT and TOT procedures, and this can safely be quoted to patients in preoperative discussion.

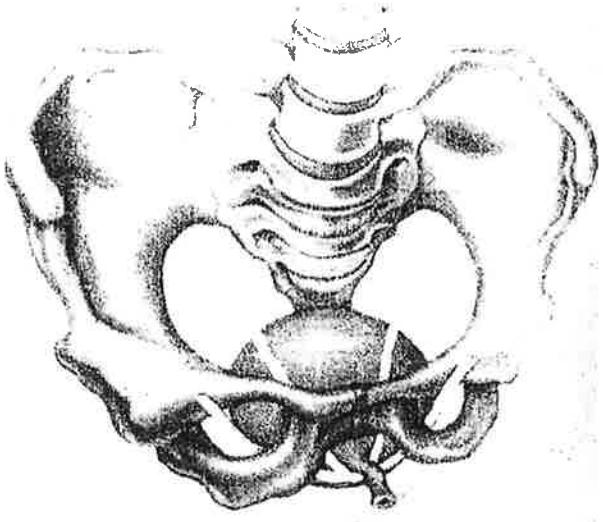


FIGURE 37.12. Comparison of retropubic and transobturator placement of TVT and TOT. The TOT is more horizontal and may therefore have less voiding dysfunction.

When the tension-free tape procedures are done in conjunction with other pelvic floor surgery, it does not seem to matter as to the order in which things are done. The tape can be laid in position initially and then the rest of the procedures completed and the tape tightened at the end of the case. If there is a lot of bleeding from dissection for the tape, this can cause some delay and interference with the rest of the case. The other way is to do all the other procedures, and then place the tape at the end. Any anterior vaginal wall dissection should not extend closer than 2 cm to the urethral meatus, thus leaving room for the tape dissection. If a colpocleisis is performed, the tape has to be placed before obliterating the anterior wall.

Suburethral Slings

The concept of placing a material under the urethra and suspending it to the abdominal tissues was introduced as early as 1907 when Giordano used gracilis muscle transposed beneath the bladder neck. Goebell (1910) used pyramidalis muscles transposed through the space of Retzius, and first Frangenheim (1914) and then Stoeckel (1917) described using a strip of anterior abdominal fascia with the pyramidalis muscles. Price (1933) harvested fascia lata, which he passed beneath the urethra and then retropubically, and attached it to the anterior rectus fascia on either side of the midline. This technique and its modifications became known as the Goebell-Stoeckel-Frangenheim procedure, or fascia lata sling, but the named surgeons never used fascia lata. Aldridge (1942) used strips of rectus fascia from a transverse abdominal incision, passed them retropubically, and secured them beneath the urethra. McGuire and Lytton (1978) described a sling procedure using rectus fascia supported by sutures extending through the space of Retzius and attached to the rectus fascia. This procedure and its modifications are referred to as a rectus sling.

The sling acts like a hammock under the bladder neck to both elevate the urethrovesical junction into an intraabdominal location and to provide partial compression of the urethra. These techniques differ from the modern tension-free procedures because the ends of the sling or suspending sutures are fixed to the rectus fascia. During periods of increased abdominal pressure, the abdominal wall moves outward and the sling is drawn upward. This compresses the urethra and increases intraurethral resistance. Variations of the sling procedure in which the ends of the sling are attached to an immovable tissue (Cooper's ligament or bone anchors in the pubic symphysis) do not allow upward displacement of the sling and urethra during straining. In these operations, the sling is thought to create a secure platform of urethral support. Increases in intraabdominal pressure press the urethra downward against the sling, thereby compressing the urethra from both above and below. It is this compression of the urethra that is believed to lead to increases in urethral resistance and a resolution of stress incontinence. However, the potential for excess compression of the urethra also contributes to the most common complications of the sling procedure: voiding dysfunction.

The intervening 100 years have provided time for development of many materials and techniques for sling surgery. The autologous tissues have included rectus fascia, fascia lata, vagina, gracilis muscle, round ligaments, pyramidalis muscle, and rectus muscle. Because of additional operative time and morbidity to harvest autologous materials, many substitute materials were used and evaluated. Synthetic materials are now almost completely confined to polypropylene mesh. Biomaterials have included human-derived dermal and fascial tissues, with fascia lata composing most of the active use. Allograft fascia materials have been in use for more than 25 years but have to be harvested, processed, preserved, and distributed by tissue banks regulated by the American Association of Tissue Banks. Xenograft materials are mostly porcine dermis and bovine pericardium.

Surgeons who prefer an autologous sling use either rectus fascia or fascia lata. Rectus fascia is harvested at the time of a suprapubic incision by excising a strip of rectus fascia and closing the residual defect. A 4- to 5-cm incision easily allows harvest of a fascial strip 2 cm wide and 8 to 10 cm long (Fig. 37.13). A fascial closure suture is placed beyond the harvest site on both sides and a strip of rectus fascia developed medially from each side. The graft is wrapped in saline-soaked gauze or placed in an antibiotic solution. The fascia is mobilized sharply off the underlying muscle to avoid tension in the closure. The rectus fascia is cleared of fat just above the symphysis pubis on either side to allow for fixation of the sling.

Alternatively, fascia lata may be harvested from the lateral aspect of the thigh (Fig. 37.14) using a Masson stripper or a Crawford fascial stripper. Alternatively, the fascia may be excised directly. The Masson stripper comes in 1-cm and 2-cm sizes and can remove a strip up to 3 cm in width and 20 cm long. The Crawford stripper can remove a strip 1 cm wide and 20 cm long.

Harvest is accomplished with the patient supported leaning to one side and the leg positioned on a pillow (Fig. 37.15). The iliotibial fan of fascia is palpated over the lateral thigh near the knee. A vertical or transverse incision is made 2 to 3 cm above the knee over the fascia and the fascia lata cleaned with a gauze-tipped finger. Two incisions are made in the fascia, 1.5 to 2 cm apart, and the fascia lata transected 3 to 4 cm superior to its attachment into the lateral condyle of the femur. The distal 4 to 5 cm of fascia is mobilized with sharp dissection and the free end threaded into the Masson or Crawford fascial stripper and held firmly with straight Kocher clamps. The fascia is freed superiorly from attachments by passing a long forceps (handle end) over the superior and inferior surfaces of the fascia. The stripper is then advanced parallel to the fascia lata fibers, toward the greater trochanter of the hip (Fig. 37.16). The Masson stripper has an inner and outer component, and the outer

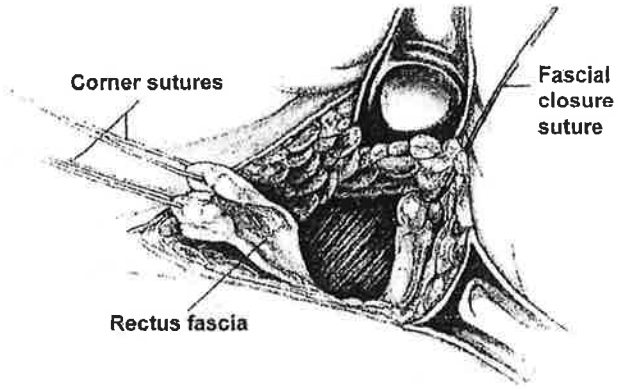


FIGURE 37.13. Rectus fascial harvest. A fascial closure suture is placed where the fascia is mobilized laterally in order to assist in closure of the residual defect. Corner sutures on the harvested fascia assist in the mobilization of the strip and are used later in passage from the vaginal to the abdominal site. (With permission: Brubaker L. Suburethral sling procedures. *Operative Techniques in Gynecologic Surgery* 1997;2:46.)

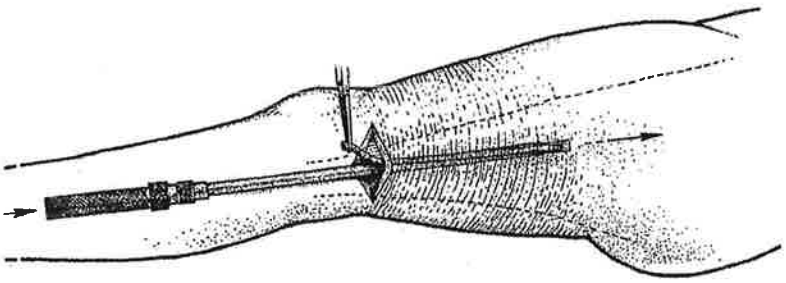


FIGURE 37.14. Masson fascial stripper. (With permission: Ridley JH. Surgery for stress urinary incontinence. In: Ridley JH, ed. *Gynecologic surgery: errors, safeguards, salvage*. Baltimore: Williams & Wilkins; 1974:135.)

sheath is disengaged and advanced briskly or turned over the inner portion, which severs the fascia at the uppermost area of the leg. The Crawford stripper requires a pulley action to advance a cutter at the end of the instrument to cut the fascial strip. The 1-cm-wide strip obtained with the Crawford stripper requires a second pass to get a second strip if a full-length sling is desired, and the two are sutured together, overlapping in the center 2 or 3 cm, to make that area thicker as well as wider. The open technique requires two vertical incisions separated by an intact skin area at least the size of each incision. The fascia lata is dissected free from the muscle underneath, and elevation of the skin bridge allows dissection to the higher incision. The fascia is cut 2 to 3 cm wide, and the uppermost end is severed to procure the strip. The fascial defect is not closed, but a pressure dressing is usually applied, and the skin may be closed with a subcuticular suture.

Sling length has varied in the many procedures described. A patch sling is several cm in length, but the tails of the sling do not perforate the endopelvic fascia into the retropubic space. The patch is suspended by permanent sutures and allows harvest of small amounts of tissue, but there is little *in situ* scarring and fixation of the fascial material. A full-length sling passes underneath the urethra, through the endopelvic fascia and retropubic space, all the way to the point of fixation, where it is secured with sutures. Usually the fixation point is rectus fascia. A half sling (7 cm length or more) extends into the retropubic space through the endopelvic fascia and is attached by sutures secured to the tails to suspend the material to the appropriate fixation site, usually the rectus fascia. This has become the most common sling length when using autologous materials. A full-length sling extends all the way to the fixation site, rectus fascia, or Cooper's ligament, where it is attached.

The abdominal dissection is performed through a 4- to 5-cm incision (unless the patient is obese) usually placed 2 cm above the symphysis pubis, but not in the crease of the panniculus. The fascia is cleared of fat and subcutaneous tissues at sites 2 cm above the symphysis and 2 cm lateral to the midline, where the sling arms or sutures will be passed through the fascia. If an instrument is used to grasp the sling or suture tails (as opposed to a needle passer technique using Pereyra or Stamey needles), then a small 0.5- to 1-cm incision is made in the full-thickness rectus fascia. If rectus fascia has been harvested, the remaining lower margin of fascia is cleared of fat and subcutaneous tissue.

The retropubic space may be opened, especially in cases in which there has been previous retropubic surgery. If necessary, the bladder can be opened at the dome to facilitate sharp dissection of the bladder away from the sidewall of the pelvis. In this technique, a finger can be placed through the abdominal incision reaching to the level of the endopelvic fascia. The vaginal dissection extends to the same level, and the sling material can easily be passed from vaginal to abdominal surgeon without concern regarding placement of the sling in the bladder or through a segment of bowel. This can still be accomplished through a small (5-cm) skin incision.

The vaginal dissection commences with an inverted U or 2-cm midline incision along the anterior vaginal wall. The epithelium is dissected off the fibromuscular layer laterally until access through the endopelvic fascia is readily available beneath the descending pubic ramus. The epithelial flap may be left thick to protect against poor healing of the vaginal epithelium over the sling material. The fibromuscular layer does not need to be plicated unless extra thickness is desired under a synthetic sling or there is a central anterior vaginal wall defect. Sharp dissection to the level of the pubic ramus allows easy access to perforate the endopelvic fascia sharply or bluntly,

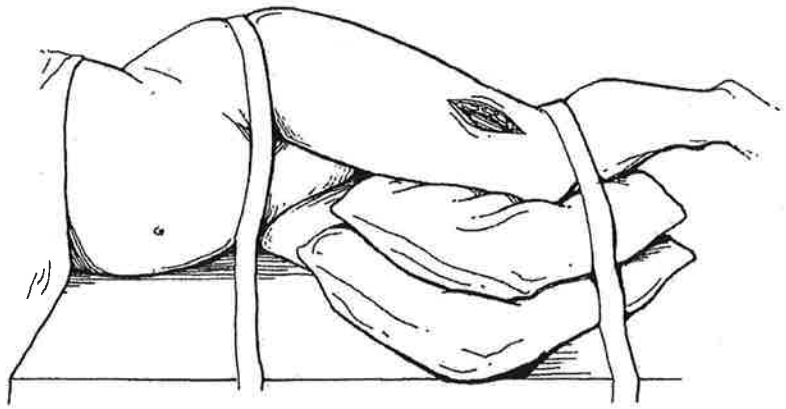


FIGURE 37.15. Patient positioning for fascia lara harvest. An incision is made over the fascia lata approximately 3 to 4 cm above the knee.

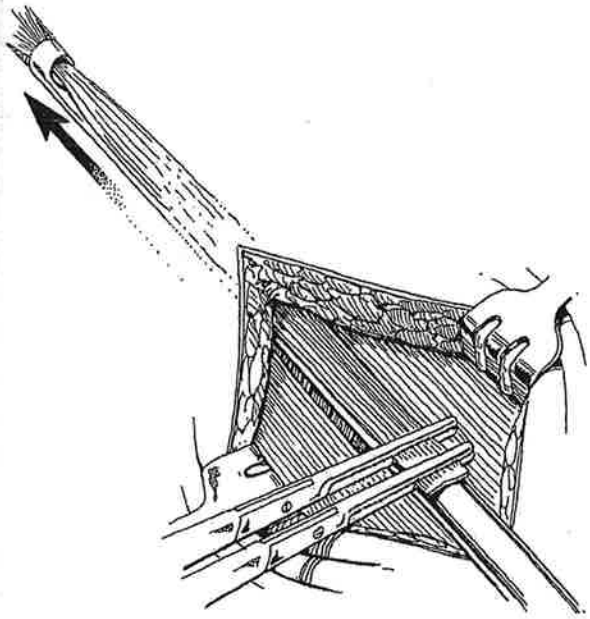


FIGURE 37.16. Harvesting fascia lata. With the fascial end secured by Kocher clamps, the stripper is slowly advanced parallel to the fascia lata fibers, shearing off a long strip of fascia.

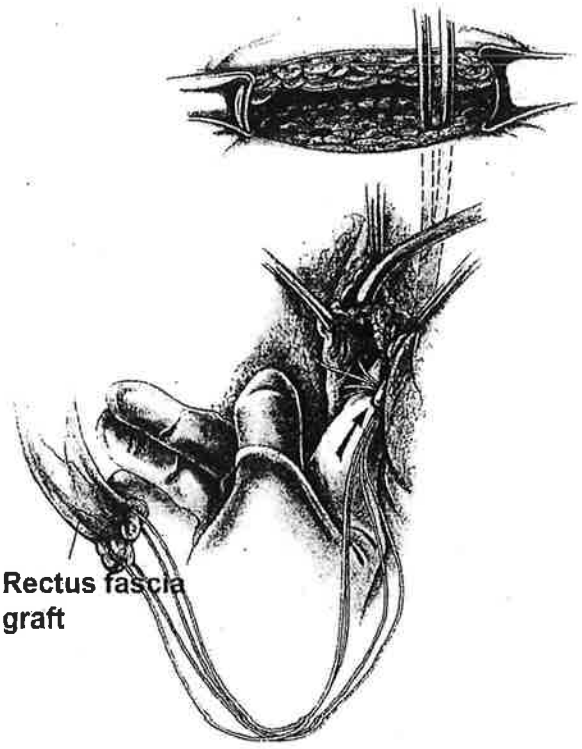


FIGURE 37.18. Passage of sling material through the space of Retzius from vaginal to abdominal site. Rectus fascia partial sling with attached sutures. (With permission: Brubaker L. Suburethral sling procedures. *Operative Techniques in Gynecologic Surgery* 1997;2:48.)

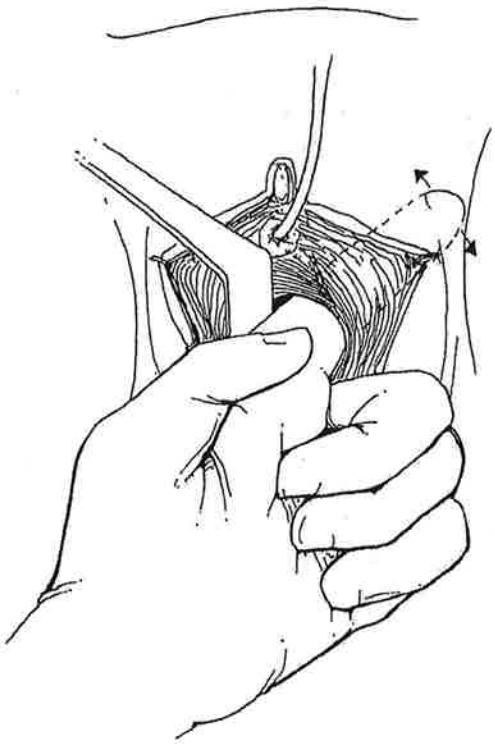


FIGURE 37.17. Perforation of the endopelvic fascia to open the space of Retzius and mobilize the periurethral tissues.

directing the instrument or finger toward the ipsilateral shoulder (Fig. 37.17). Some surgeons do not enter the retropubic space when placing a sling. Others use a finger to guide an instrument or needle pass from the abdominal to the vaginal incision, and this is the recommended technique. The instrument is directed through the abdominal incision and directed toward the back of the symphysis pubis. A finger placed in the vaginal dissection reaches to the retropubic space to meet the advancing clamp or needle to minimize the distance of blind passage (Figs. 37.18 and 37.19). Cystoscopy ensures bladder integrity and ureteral function. The sling is sutured to the pubocervical fascia under the mid- to proximal urethra to prevent movement from the placement site. A Foley catheter bulb marks the bladder neck. Historically, the position of the sling was bladder neck and proximal urethra (Fig. 37.20). With the introduction of the tension-free tape procedures at the midurethra, a number of surgeons have also moved traditional suburethral sling placement more distally to override the midurethra. A broad-based sling is considered preferable to a narrow band of material.

The most common fixation site is rectus fascia (Fig. 37.21). The arms of the sling or suspending sutures may be secured together loosely over the rectus fascia without actually being sutured to the fascia. Cooper's ligament can also be used to support the sling arms. Bone anchors allow alternative fixation to a solid structure, although there is no evidence that weak rectus fascia attachment is a cause of procedure failure. The sutures or sling tails are placed through the fascia and tied with 1 to 3 finger breadths between the tissue and the sutures or sling. The object is to leave the sling loose.

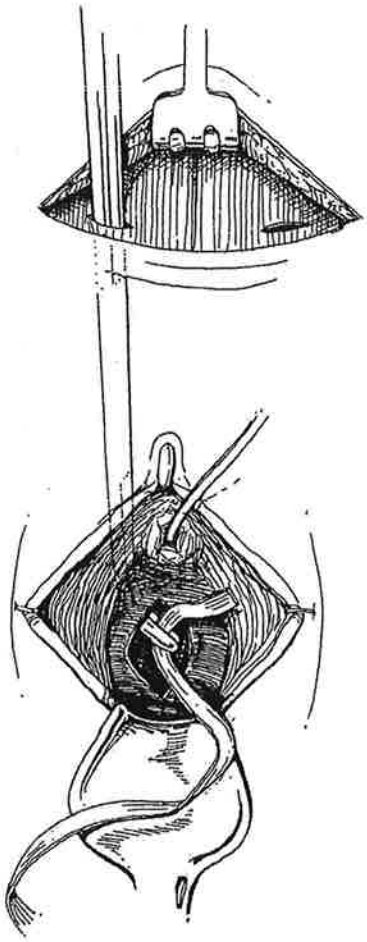


FIGURE 37.19. Passage of fascia lata strip through space of Retzius. Under guidance from the surgeon's hand in the vaginal incision through the endopelvic fascia into the space of Retzius, a clamp is passed from the abdominal incision to the vaginal incision. The end of the fascia is grasped and retrieved to the abdominal site.

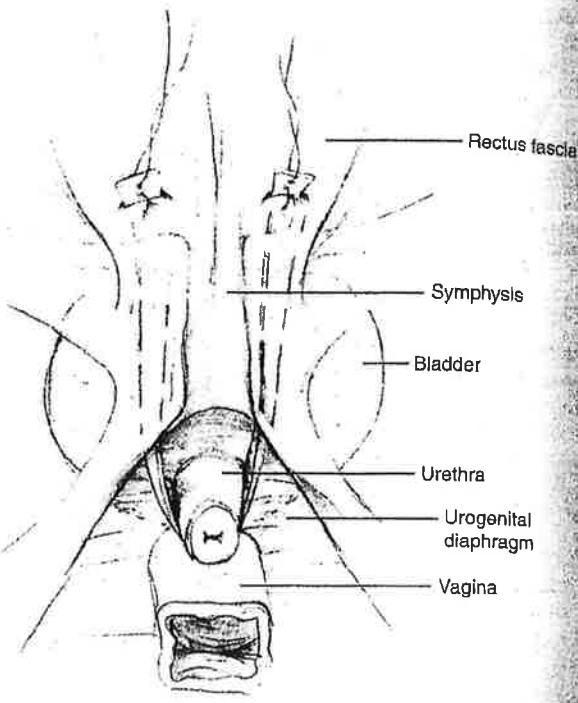


FIGURE 37.20. Sling positioned at proximal urethra, extending through the space of Retzius, and fixed to the rectus fascia.

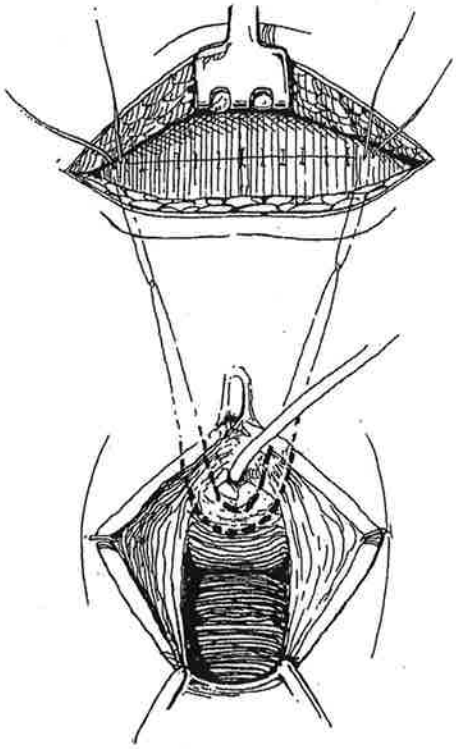


FIGURE 37.21. Rectus sling. Sutures sewn into each end of the fascial strip are passed through the space of Retzius on each side and secured to the rectus fascia.

Bladder drainage techniques include suprapubic catheter, Foley catheter, or intermittent self-catheterization. Most often, a Foley catheter is left overnight and then removed the following day, allowing the patient the opportunity to void. Postvoid residual urine determinations are measured by bladder scan or catheterization; if voiding is not adequate, the Foley catheter may be reinserted or self-catheterization used. There is no uniform residual urine determination considered normal, but it should be less than 200 mL, with a reasonable voided amount equal to or two times greater than the residual amount.

Hospital length of stay is variable but often is only 1 day. Patients should avoid strenuous exercise and heavy lifting for 3 months. Intercourse and vaginal inserts should be avoided until there is good vaginal healing. There is no need to restrict showers or shallow tub baths.

Complications (Table 37.7) are addressed before surgery by use of preoperative antibiotics to prevent infection and use of compression stockings or heparin to prevent deep venous thrombosis (DVT). Early mobilization and use of an incentive spirometer help avoid DVT and respiratory problems. The

TABLE 37.7

COMPLICATIONS OF CONVENTIONAL SUBURETHRAL SLINGS

Complication	Frequency (%)	Resolution
Bleeding with vaginal dissection	20	Pressure, cautery, suture, packing
Retropubic space bleeding	5–10	Spontaneous absorption
Bladder perforation	1–2	Replace sling, leave catheter 2 to 3 days
Infection—wound	<5	Eventual healing
Wound seroma—leg or abdomen	3–5	Closed drainage
Infection—urine	20	No long-term sequelae
Retropubic space hematoma	2	Slow resorption
Retropubic space abscess	Infrequent	Drainage: open vs. imaging technique
Blood clot (deep venous thrombosis)	2–30	Aggressive treatment, prevention
Respiratory problem	2–5	Incentive spirometer, physiotherapy
Vaginal breakdown over sling	1–2	Soaks, local irrigation, antibiotics
Mesh erosion	5–25	Local excision, revision, and resuture
Voiding dysfunction	2.5–24	Patience, self-catheterization, medication
Obstructed voiding	1–2	Sling release
De novo urge incontinence	3–23	Bladder retraining, medication
Persistent urge incontinence	26–60	Bladder retraining, medication
Urethral erosion	Rare	Sling removal; surgical repair

usual intraoperative complication of surgery is bleeding. Large veins under the descending pubic ramus may be avulsed during the vaginal portion of the procedure, and there are often vessels on the medial side of the vaginal dissection into the retropubic space. The latter ones can be isolated and cauterized or sutured, but the ones under the pubic ramus are best controlled by pressure, completion of the procedure, and placement of a vaginal pack. Large vessels of the pelvis are seldom penetrated by instruments or sling. The sling may be passed through the bladder and may have to be removed and repassed. On rare occasions, the sling or a suprapubic catheter may be placed through a portion of bowel, and recognition of this complication can be delayed. Temperature elevation is rare but may be caused by atelectasis, pneumonia, and hematoma in the early postoperative period. Cystitis, pyelonephritis, bowel injury, and wound infection are not usually obvious for a few days. Voiding function and possible bladder overdistension must be monitored carefully.

Short-term complications include continued voiding difficulty, bladder infection, and overactive bladder symptoms. A wound seroma or infection may occur at either the abdominal incision site or at the fascial harvest site. If a significant hematoma has occurred in either the abdominal incision or retropubic space, abscess formation may follow. Vaginal healing may be compromised by delayed healing of the anterior vaginal wall, oozing or bleeding from the suture sites, and failure of the incision to close properly over the sling.

Long-term complications include voiding dysfunction, overactive bladder symptoms, and procedure failure. If the patient is unable to void at all, the sling may need to be incised. The occurrence of a vaginal erosion is usually a delayed event with synthetic materials, and this area of incomplete healing can be difficult to resolve.

The cure rate for sling procedures is more than 80% for all procedures, primary and repeat. Traditional suburethral sling procedures have long-term durability, effectiveness in cases with impaired urethral sphincter function or restricted mobility of the bladder neck, and applicability to primary cases with minimal risk of complications.

Periurethral Bulking Procedures

The major impetus for use of periurethral bulking in the United States came in 1993 when the U.S. Food and Drug Administration approved the use of Contigen®. This was followed in July 1994 by Medicare's approved payment for the service based on a number of criteria. These criteria were altered in 1996 and included the presence immobility of the bladder neck, as well as a leak point pressure less than 100 cm of water. The ideal patient is one who meets the above criteria with a fixed bladder neck (Q-tip straining angle 40 degrees or less), who is medically compromised and/or elderly, and in whom an operative intervention may offer too much risk. Also, some patients prefer to use a less invasive technique. There are still little data on effectiveness of minimally invasive midurethral slings in patients who have a scarred bladder neck; although a traditional suburethral sling has a very good cure rate, it is invasive and is associated with greater risk and complications.

The ideal material is biocompatible, nonimmunologic, and hypoallergenic. It should be inexpensive and easy to inject, and it should not migrate. Materials approved for use or in studies are shown in Table 37.8. Methods of injection include periurethral, transurethral through the cystoscope, or transurethral using an injector device that fits in the urethra. The ideal setting for injection is the office or clinic. No preoperative sedation is

TABLE 37.8

PERIURETHRAL BULKING AGENTS IN NORTH AMERICA

Trade name	Company	Approval
Contigen®	C R Bard Inc., Atlanta, GA	1993
Durasphere®	Boston Scientific, Boston, MA Carbon Medical Technologies Inc., St. Paul, MN	1999
Tegress	C R Bard Inc., Atlanta, GA	2004
Macroplastique®	Uroplasty, Minneapolis, MN	FDA trials ongoing[a] Approval in Canada
Zuidex™	Q-med, Uppsala, Sweden	FDA trial ongoing[b]
Coaptite®	Genesis Medical Ltd, London, UK	FDA trials ongoing[c]
Permacol™	TSL, Aldershot, Hampshire, UK	FDA trials starting

FDA, U.S. Food and Drug Administration.
[a]Ghoniem G. Transurethral Macroplastique® injection for treatment of female stress urinary incontinence: office-based technique. Paper presented at: International Urogynecological Association 28th Annual Meeting; October 2003; Buenos Aires, Argentina (abstract 36).
[b]Larsson G, Fienu Jonesson A, Farrelly E, et al. Efficacy and safety of dextranomer/hyaluronic acid via a novel applicator (Zuidex®) in the treatment of stress urinary incontinence. Paper presented at: International Continence Society 33rd Annual Meeting; October 2003; Florence, Italy (abstract 400).
[c]Dmochowski, Appell R, Klimberg I, et al. Initial clinical results from Coaptite® injection for stress urinary incontinence comparative clinical study. Paper presented at: International Continence Society 32nd Annual Meeting; September 2002; Heidelberg, Germany (abstract 282).

required. The injection is performed in a sterilized field by using no-touch technique.

Periurethral Injection

The patient empties her bladder and is placed in lithotomy position. Local anesthesia using 0.5 to 1.0 mL of lidocaine hydrochloride is injected 0.5 cm on either side of the urethral meatus (Fig. 37.22). Under endoscopic guidance, lidocaine 1% solution is injected parallel to the urethra in small amounts until the proximal urethra is reached and the needle or injection can be seen distending an area 1 cm distal to the bladder neck. The syringe with lidocaine is replaced with a syringe of bulking agent, and the material is injected until the entire syringe has been injected or there has been adequate effect noted with urethral bulking. The process is repeated on the opposite site, but the second side is more difficult to inject because of the distortion caused by the initial injection (Fig. 37.23).

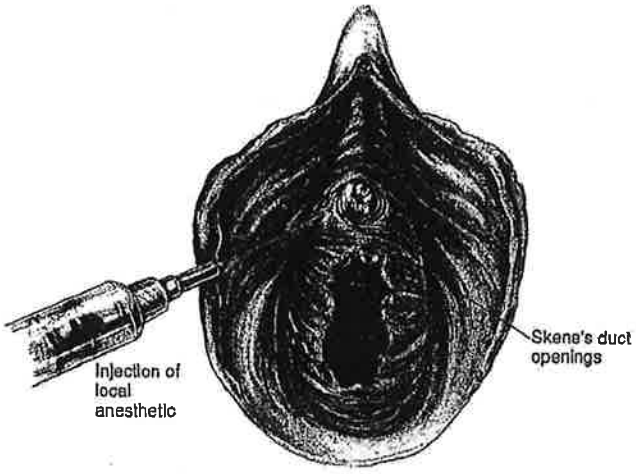


FIGURE 37.22. Periurethral bulking technique. Injection of local anesthetic lateral to Skene duct openings. (With permission: Bent AE. Periurethral collagen injections. *Operative Techniques in Gynecologic Surgery* 1997;2:52.)

Transurethral Injection

The transurethral method is best accomplished using a cystoscope with a 12-degree or 25-degree lens. The sheath has no fenestration, and the operating channel allows the passage of a disposable injection needle with a guide or a reusable needle. Alternatively, a spring-loaded mechanism is favored by some operators. The needle is prefilled with lidocaine 1% solution, the syringe with bulking material is attached, and the cystoscope with injection needle retracted is placed into the bladder. The bladder neck is identified, and the scope is withdrawn to visualize the proximal urethra. The usual injection sites are 3 and 9 o'clock, but this can be varied depending on user preference and number of injection sites selected (up to four). The injection needle is advanced into the urethra submucosa approximately 2 cm distal to the bladder neck (Fig. 37.24), and the injection of material is preceded by the small amount of local anesthetic solution. The needle is advanced 1 cm, and the bulking material is injected. The injection needle is flushed with lidocaine at the first site, and then the second site is selected.

A pressure system is required for transurethral injection of Macroplastique. Injection needles vary in diameter according to the ease of injection of the selected material.

An insertion device is available for Macroplastique and for Zuidex. Transurethral injection is facilitated without

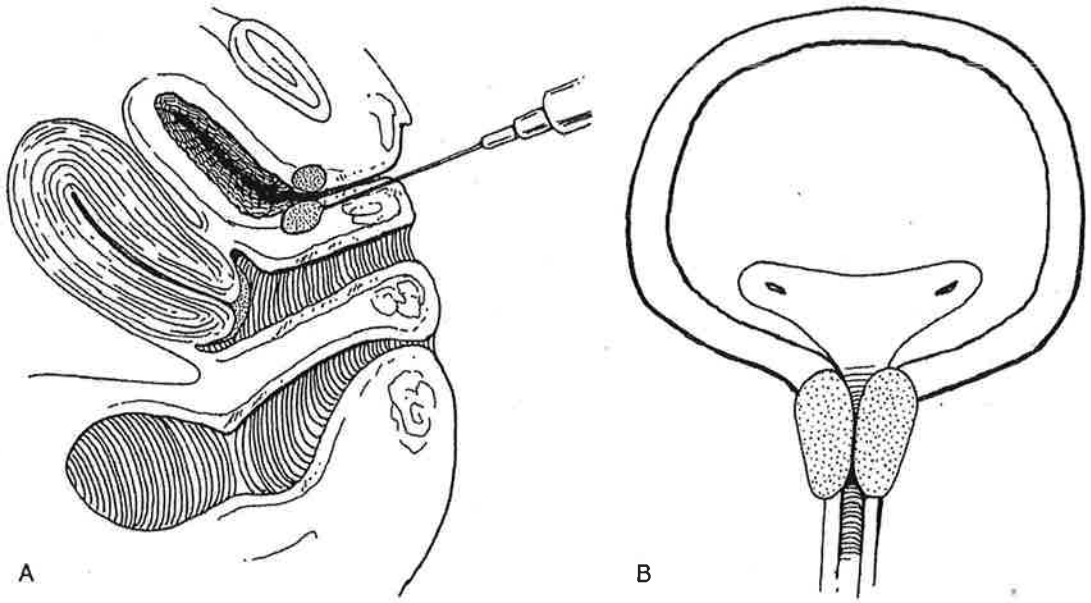


FIGURE 37.23. A: Periurethral injection at the bladder neck. B: Bulking of bladder neck and proximal urethra.

visualization of the injection site. The device has four angled ports for four needles; after measurement of the urethral length, the device is inserted into the urethra to allow placement of the material at the desired submucosal depth in the mid- to proximal urethra. The efficacy reports are still in early stages, and the more traditional injection techniques are the current recommendation.

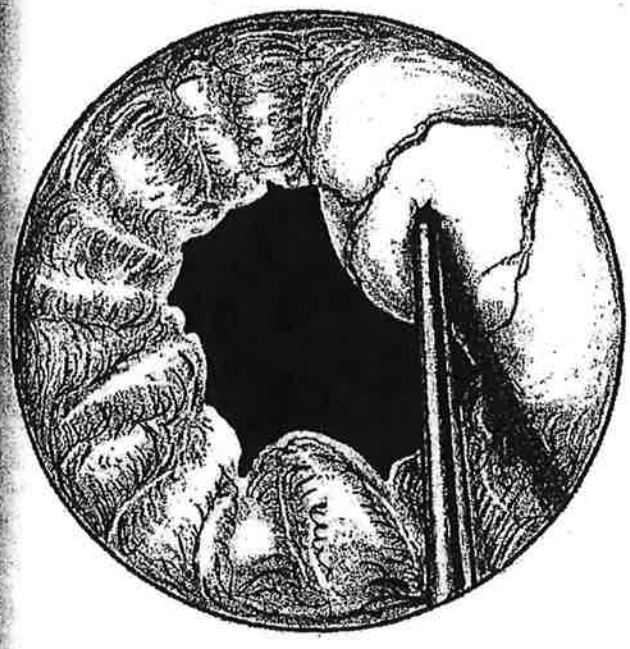


FIGURE 37.24. Transurethral needle placement in urethral submucosa. (With permission: Bent AE. Periurethral collagen injections. *Operative Techniques in Gynecologic Surgery* 1997;2:54.)

After injection, the patient may have urethral burning that lasts for only part of a day and can be controlled with phenazopyridine (Pyridium). Antibiotics are prescribed for 1 to 2 days after injection because the rate of urinary tract infection is high. The patient attempts voiding after the injection, and she should be prepared to stay in the clinic area for 1 to 2 hours to allow the initial swelling from the injection to diminish. If the patient is unable to void or she has a high residual urine, she either needs to be instructed in self-catheterization or have a small catheter (8 to 10 French Foley) placed, using no more than 5 mL in the balloon. Patients should be called or seen the day following the injection to be sure there is no continuing problem. At follow-up, assessment is made for voiding function, urinary tract infection, and swelling at the injection site. Effectiveness is assessed, and overactive bladder symptoms are managed as appropriate.

One or two injections may be required to obtain a satisfactory result; if there is no improvement at that point, additional injections are not indicated. The success rate is generally quoted to be about 70%. Most injections last 6 months to 2 years and then have to be repeated. There is no limit to the number of injections provided that improvement occurs after each injection and lasts a reasonable period of time. There is no advantage of any particular bulking agent, and selection is usually based on operator experience, ease of injection, cost, and availability of the product.

ARTIFICIAL URINARY SPHINCTER

The ultimate treatment of urinary incontinence secondary to intrinsic sphincter deficiency is implantation of an artificial urinary sphincter. The device consists of a small inflatable cuff, a pump (which usually is implanted within one of the labia

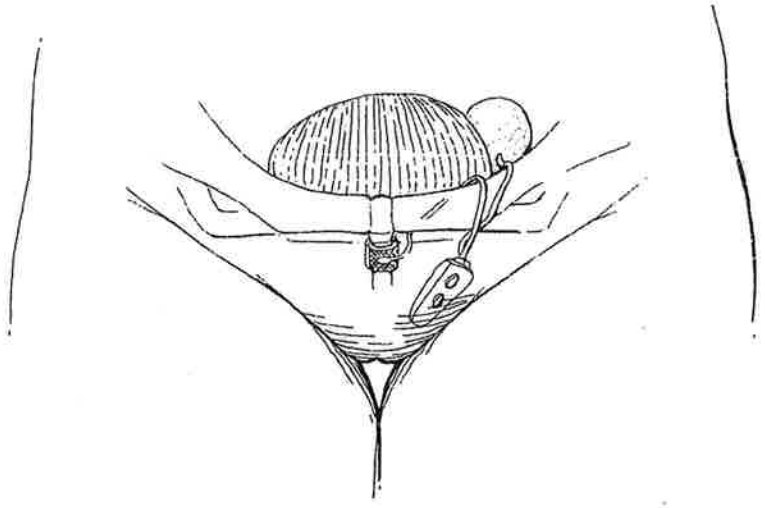


FIGURE 37.25 Artificial urinary sphincter.

majora), and a reservoir, which is placed in the abdomen beneath the fascia (Fig. 37.25). The cuff is placed around the bladder neck and proximal urethra usually through a combined vaginal and abdominal approach. After allowing 6 weeks for healing to take place, the cuff is inflated to compress the urethra. Once inflated, the cuff maintains urethral closure until the patient needs to void. The patient deflates the cuff by squeezing the labial pump, moving fluid from the cuff into the reservoir. After voiding, the cuff automatically reinflates from the reservoir over 1 or 2 minutes and remains closed until the pump is reactivated.

There are a number of complications related to artificial urinary sphincter, including cuff erosion, infection, and device failure. The device is not indicated as a primary treatment for SUI and should only be inserted by an experienced surgical team working in an isolated and controlled operative environment.

SUMMARY

The surgical management of SUI has developed over almost 100 years. Only recently have randomized controlled trials been conducted, and new procedures are often introduced with little long-term efficacy or complication risk data. One of the problems has been the numerous modifications surgeons like to make on other procedures, thus producing yet another new approach.

More recently, instrument manufacturers have introduced a multitude of new instruments and new tape materials for the tension-free midurethral tape procedures with very little clinical data to support their safety or efficacy, much less any comparison with older, established procedures or equipment. The basic evaluation of incontinence includes history, physical examination, measurement of postvoid residual urine, and urinalysis. Preoperative assessment may include a measure of urethral mobility, 24-hour voiding diary, cough stress test, symptom questionnaire, and cystometry. Long-term data indicate the Burch colposuspension and tension-free tapes have similar cure rates. Anterior repair, needle procedures, and paravaginal repairs are not indicated for SUI.

BEST SURGICAL PRACTICES

- There are two types of SUI: hypermobility (or anatomic) and intrinsic sphincter deficiency. Most patients have elements of both causes for their incontinence but in varying degrees for each.
- Evaluation before surgery for SUI includes history, physical examination, pelvic examination, voiding diary, symptom questionnaire, residual urine determination, Q-tip test for urethral mobility, and urinalysis. If there is any concern regarding symptoms or prior procedure failure, then cystometrics and cystoscopy should be performed.
- The approach for primary SUI is a tension-free midurethral sling, Burch retropubic urethropexy, or other suburethral sling.
- The approach for recurrent SUI and a scarred bladder neck is most often a suburethral sling.
- The tension-free vaginal tape procedures have revolutionized surgery for stress incontinence, bringing it into the realm of minimally invasive day surgery. The principles for tension-free slings are to place them at the midurethra without tension. There are numerous brands, but the essence is a polypropylene mesh sling, 1 cm in width, placed by insertion needles and small incisions. Cystoscopy is recommended to assure there is no bladder injury. There are suprapubic as well as transobturator techniques without obvious proven advantages of one kind over another. The cure rates are all close to 85%. The procedures may be combined with other pelvic floor reconstructive surgery. Complications are minimal and include voiding dysfunction, overactive bladder, and mesh erosion.
- Standard suburethral slings are best performed with harvested autologous materials, either rectus fascia or fascia lata. The vaginal dissection should allow minimal blind passage from the vaginal to the abdominal site. Fixation is loosely accomplished to rectus fascia so as to avoid voiding dysfunction.
- Periurethral bulking has a place in medically compromised or elderly patients, especially for those with severe incontinence and minimal mobility of the bladder neck, i.e., Q-tip test <40 degrees straining.

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